

**REMARKS**

Claims 1-48 were originally filed. Claims 49-108 were previously added. Claims 1-59, 61-64, and 85-87 were previously canceled. Therefore, claims 60, 65-84, and 88-108 are currently pending. No new matter is added by way of the amendments presented above. Reconsideration of the present application in view of the amendments above and the remarks below is respectfully requested.

**Rejection Under 35 U.S.C. § 112, First Paragraph is Withdrawn**

Applicants note that the rejection of claims 60 and 65-84 under 35 U.S.C. § 112, first paragraph, as set forth in the Office Action mailed May 21, 2003, is withdrawn in the present Office Action mailed June 25, 2004 (hereinafter, the "present Action").

**Claim Objections**

Claim 60 is objected to because it includes the informality of repeating SEQ ID NO:15 twice. Original claim 15 in priority application PCT/US97/09099 (WO 97/45447), which corresponds to claim 60 in the present application, recites, "The method of claim 11 wherein said polypeptide includes an amino acid residue sequence shown in SEQ ID NO 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21 or 22" (a copy of the claims from PCT/US97/09099 is enclosed for the Examiner's convenience). Thus, it is clear that the second "15" in claim 60 was a typographical error and should have read "16" instead of "15". Claim 60 is amended above to correct this obvious typographical error.

Furthermore, SEQ ID NO:18 was inadvertently left out of claim 60, but was included in corresponding claim 15 in

priority application PCT/US97/09099. Thus, claim 60 is amended above to add SEQ ID NO:18 to claim 60 in order to correct this error.

New Rejection Under 35 U.S.C. § 112, First Paragraph

Claims 60 and 65-84 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The present rejection is respectfully traversed for the reasons set forth below.

The Examiner alleges that, in regard to claim 60 (and, therefore, claims 65-84 which depend therefrom): that Applicants have not provided sufficient evidence that they were in possession of the infinite number of polypeptides that include the denoted sequences, that the recited antagonist could be just a single amino acid residue, that the skilled artisan cannot envision the detailed structure or activity of potential antagonists comprising any one of the said sequences and therefore conception is not achieved until reduction to practice has occurred, and that the full breadth of the claims do not meet the written description provision of 35 U.S. C. 112, first paragraph.

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See, e.g., *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319, 66 USPQ2d 1429, 1438 (Fed. Cir. 2003); *Vas-Cath, Inc. v.*

*Mahurkar*, 935 F.2d at 1563, 19 USPQ2d at 1116. (See, also, MPEP 2163, page 2100-164, 8th Ed., Rev. 2, May 2004.)

An applicant may show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that applicant was in possession of the claimed invention, i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics (emphasis added). *Enzo Biochem*, 323 F.3d at 964, 63 USPQ2d at 1613. (See, also, MPEP 2163, page 2100-171, 8th Ed., Rev. 2, May 2004.)

Applicants respectfully submit that the polypeptides recited in the method of claim 60 do recite sufficient structure to demonstrate to one skilled in the art that the invention was complete at the time the application was filed. Specifically, the polypeptides recited in claim 60 include, as amended above, an amino acid residue sequence shown in SEQ ID NO 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21 or 22. Therefore, the written description requirement is fulfilled by the description provided in the specification of the present application because one of skill in the art will recognize that the claims recite sufficient structure to demonstrate that the invention was complete at the time the application was filed.

Furthermore, conception occurs when one has a mental picture of the structure of the chemical, or is able to define it by its method of preparation, or whatever characteristics are sufficient to distinguish it from other materials. See, e.g., *Fiers v. Sugano*, 25 USPQ2d 1601, at 1604 (Fed. Cir. 1993).

Applicants respectfully submit that the claims do recite sufficient structure of the chemical, i.e., the polypeptides recited in the method of claim 60, to distinguish the recited polypeptides from other materials. Therefore, the present rejection should be withdrawn because the claims recite sufficient structure such that one skilled in the art can distinguish the polypeptides recited in the method of claim 60 because the claims recite specific amino acid sequences included in the polypeptides.

By way of further argument, Applicants respectfully submit that the Examiner's rejection of claims 60 and 65-84 amounts to a prohibition against the use of the transitional term "comprising" as applied to claims that recite polypeptides because, as the Examiner states at page 3 of the present Action, "In essence the sequences are amongst undefined amino acid residues that may exist on the amino- and carboxy- termini of SEQ ID NO:11-15, 17 and 19-22".

However, as set forth by the courts, the transitional term "comprising" which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., *Invitrogen Corp. v. Biocrest Mfg., L.P.*, 327 F.3d 1364, 1368, 66 USPQ2d 1631, 1634 (Fed. Cir. 2003) ("The transition 'comprising' in a method claim indicates that the claim is open-ended and allows for additional steps."); *Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997) ("Comprising" is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim.); *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 229 USPQ 805 (Fed. Cir.

1986); *In re Baxter*, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948) ("comprising" leaves "the claim open for the inclusion of unspecified ingredients even in major amounts"). (See, also, MPEP 2111.03, page 2100-052, 8th Ed., Rev. 2, May 2004.)

Thus, the present rejection should be withdrawn because the courts have made it clear that the use to the transitional term "includes", as recited in claim 60, is acceptable to describe the structure of a chemical recited in a method claim because the courts have accepted the use of the term "includes" to describe chemical structures wherein the claim is open for the inclusion of unspecified ingredients even in major amounts.

Also at page 3 of the Office Action, the Examiner asserts, "the antagonist could be just a single amino acid residue as set forth in claim 60, lines 5 and 6". The present assertion is respectfully traversed because nothing at lines 5 and 6 of claim 60 as previously presented can be interpreted to mean that the antagonist could be just a single amino acid. For example, each of the amino acid sequences recited in claim 60 by sequence identifier is greater than 50 amino acids in length and so could not be a single amino acid residue. However, in the interest of clarity claim 60 is amended herein to delete the term "residue" in order to more particularly point out the claimed invention. In view of the amendments to claim 60, it is believed that the assertion that "the antagonist could be just a single amino acid residue" is moot.

#### Allowed Claims

Applicants note that claims 88-108 are allowed.

**CONCLUSION**

Applicants believe that all claims are in proper condition for allowance. An early notification of allowance is earnestly solicited.

The Examiner is requested to contact the representative for the Applicants, to discuss any questions or for clarification. If there are any fees associated with this response, the Director is authorized to charge our Deposit Account No. 19-0962.

Respectfully submitted,

Oct. 19, 2004  
Date

  
Michael J. McCarthy, Reg. No. 46,910

THE SCRIPPS RESEARCH INSTITUTE  
Office of Patent Counsel  
10550 North Torrey Pines Road  
Mail Drop TPC-8  
La Jolla, California 92037  
(858) 784-2937